Claims

Sub A1

1. A pharmaceutical composition comprising a short acting hypnotic or a salt thereof characterised in that it consists of a timed dual release dosage form adapted to release the short acting hypnotic over a predetermined time period, according to an *in vitro* profile of dissolution when measured in a rotating paddle apparatus of the European pharmacopoeia in aqueous buffer at 37°C, comprising two release pulses, the first being immediate and the second being delayed by a fixed time after the administration.

2. A pharmaceutical composition according to claim 1, characterised in that the first pulse has a maximum duration of 30 minutes.

3. A pharmaceutical composition according to claim 1 or 2, characterised in that the fixed time is between 50 and 200 minutes.

4. A pharmaceutical composition according to claim 3, characterised in that the fixed time is between 60 and 150 minutes.

5. A pharmaceutical composition according to any one of claims 1 to 4, characterised in that 40 to 70% of the total amount of the short acting hypnotic is released during the immediate release pulse.

6. A pharmaceutical composition according to any one of claims 1 to 5, characterised in that the delayed release pulse lasts between 30 and 200 minutes.

7. A pharmaceutical composition according to any one of claims 1 to 6, characterised in that the time for release of 85% of the total amount of the short acting hypnotic is between 2 and 6 hours.

8. A pharmaceutical composition comprising a short acting hypnotic or a salt thereof, according to anyone of claims 1-7, characterised in that it comprises two kinds of pharmaceutical entities: one immediate release entity and one delayed release ntity.

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9. A pharmaceutical composition according to claim 8, characterised in that it consists in a dosage form chosen among capsules, tablets, multilayer tablets, multicoated tablets.

10. A pharmaceutical composition according to claim 8 or 9, characterised in that it consists of a capsule comprising one or more immediate release tablets and one or more delayed release tablets.

11. A pharmaceutical composition according to claim 8 or 9, characterised in that it consists of a capsule comprising a mixture of delayed release particles and immediate release particles.

12. A pharmaceutical composition according to claim 8 or 9, characterised in that it consists of a capsule comprising a mixture of delayed release particles and an immediate release powder.

13. A pharmaceutical composition according to claim 8 or 9, characterised in that it consists of a tablet comprising a number of delayed release coated pellets comprising the drug imbedded in a matrix and alternatively in that

(i) the matrix comprises the drug,

(ii) immediate release non-coated pellets are mixed to the delayed release coated pellets,

(iii) the delayed coated pellets are further coated with a layer comprising the drug, allowing immediate release form that layer, imbedded in a matrix free from the drug,

(iv) the tablet consists of one or more layers comprising the delayed release pellets imbedded in a matrix free from the drug and one or more layers containing the drug in an immediate release matrix.

14. A pharmaceutical composition according to any one of claims 10 to 13, characterised in that the delayed release particles or tablets are coated with a mixture containing at least one ammonio methacrylate copolymer and the core contains a cationic surfactant.

15. A pharmaceutical composition according to any one of claims 10 to 13, characterised in that the delayed release particles or tablets are coated with a mixture containing at least one ammonio methacrylate copolymer and the core contains a zwitterionic surfactant.

16. A pharmaceutical composition according to claim 14, characterised in that the cationic surfactant is chosen among trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide.

17. A pharmaceutical composition according to claim 15, characterised in that the zwitterionic surfactants are chosen among N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithines.

18. A pharmaceutical composition according to claim 16, characterised in that the zwitterionic surfactant is cocamidopropylbetain.

19. A pharmaceutical composition according to claim 8, characterised in that the immediate release entity and the prolonged release entity are administered simultaneously but separately.

20. A pharmaceutical composition according to anyone of claims 8 to 18, characterised in that the prolonged release entity comprises a pharmaceutical acceptable organic acid which can be chosen among tartaric, malic, fumaric, lactic, citric, adipic or succinic acid and their acid salts, in the form of racemates or isomers.

21. A pharmaceutical composition according to any one of claims 1 to 20, characterised in that the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, phenotiazines or imidazopyridines.

22. A pharmaceutical composition according to claim 21, characterised in that the short acting hypnotic is chosen among triazolam, temazepam, brotizolam,

zolpiclone, (*R*)-zopiclone, zaleplon, alimemazine, zolpidem and their pharmaceutically acceptable salts thereof.

23. A pharmaceutical composition according to claim 21, characterised in that the short acting hypnotic is zolpidem or a pharmaceutically acceptable salt thereof.

24. A pharmaceutical composition according to claim 23, characterised in that the salt of zolpidem is zolpidem hemitartrate.

25. A pharmaceutical composition according to anyone of claims 1 to 24, characterised in that the composition comprises constituents which, if it is introduced into an optionally alcoholic, aqueous drink, generate visual means on contact with the latter.

26. A pharmaceutical composition according to claim 25, characterised in that the visual means are chosen among inclusion of colouring excipients, floating of the composition at the surface of the drink, formation of insoluble particles on the surface of the drink, on the brim of the glass, in the drink and/or on the bottom of the glass or a combination thereof.